

San Francisco State University

Informed consent to participate in the following research study:

Relationship of airborne manganese exposure to neurobehavioral and health status of adults

A. PURPOSE AND BACKGROUND

The researcher of this study, Rosemarie Bowler, Ph.D., is a professor emerita of Psychology at San Francisco State University. The purpose of this study is to determine if there are negative health effects from exposure to airborne manganese and other chemicals in adults. You are being invited to participate in this study because you are a long term resident (10 or more years) of East Liverpool, Ohio and between the ages of 30 and 75. Your participation in this study is completely voluntary.

B. PROCEDURES

If you agree to participate, the following will occur:

- All procedures will take place in our field office in East Liverpool.
- You will be interviewed about your health history. The interview will last approximately 15 minutes.
- You will be asked to complete questionnaires on your medical, social, and psychological history. This will take you about 60 minutes.
- You will be given tests used to measure multiple areas of cognitive functioning, such as general intellectual ability, memory, attention, learning, language, and visual and spatial skills. These tests will take no more than 75 minutes.
- Your motor functioning will be examined with tests of hand strength, balance and tremor, and dexterity. These will take approximately 15 minutes to complete.
- 12 mL (about 2 teaspoons) of blood will be drawn from a vein in your arm by a certified phlebotomist (a person trained to collect blood samples). Your blood will be securely shipped to, stored, and analyzed at the Centers for Disease Control and Prevention (CDC) Environmental Health Laboratory under the direction of the assistant chief of the laboratory, Kathleen Caldwell, Ph.D. Your blood will be analyzed for the following compounds: manganese, lead, mercury, and cadmium, in addition to iron and 2 liver enzymes.
- We will ask you to provide small amounts of your hair (a small sample taken from the back of the head underneath other hair so it will not be noticeable) as well as toenail clippings from all 10 toes. These samples will be analyzed in order to evaluate your exposure to metals.
- Your toenail and hair clippings will be securely shipped to, stored, and analyzed at the Harvard School of Public Health Trace Metals Laboratory. Your toenail clippings will be analyzed for levels of metals.
- Your participation in this study will take an average of 2.5 to 4.0 hours.

C. RISKS

- 1) When blood is drawn, there is a risk of experiencing slight pain or a prick where the needle punctures the skin. There is also a slight risk of bruising or an infection where the needle punctures the skin. In rare cases, some people may experience lightheadedness, nausea, or fainting. The certified phlebotomist is trained in recognizing and dealing with such reactions. A licensed medical doctor (M.D.) will be on call nearby at all times and will give a consultation in case of a medical emergency for appropriate emergency medical care.
- 2) Participation in research may involve some possibility of loss of privacy. This risk will be reduced to the extent possible. More information about this risk and how we will reduce it appears in the confidentiality section below.
- 3) You may feel slight fatigue during testing. Should this occur, you can choose to take a break or discontinue testing at any point.
- 4) Some of the questions in the questionnaires may be personal and sensitive in nature. You are not required to answer a particular question if you feel uncomfortable.
- 5) It is possible that results from the blood analysis could reveal serious health problems that you are not aware of. After the analysis, you will be given a report indicating all your test results, and if anything serious is found, you are advised to consult with your family doctor or a local healthcare provider.
- 6) There may be risks and discomforts that are not yet known.
- 7) The researchers, research team and sponsors of this project will not provide medical care to participants nor will they cover the cost of medical care for participants.

D. CONFIDENTIALITY

Your information will be handled confidentially. Your name will not be used in any published reports about this study. Your results will be entered into a computer database without your name or other identifiers. An ID number will be assigned to all of your test results and only **Professor** Rosemarie Bowler will be aware of your identity and ID number. The data will be handled only by research staff, all of whom will sign a special confidentiality contract, and will be entered in a password-protected computer database. All research records and test results will be stored in locked file cabinets. All electronic data and results will be kept in an encrypted document on a password-protected computer. Your information will not be released unless subpoenaed by a court of law. All biological samples will be stored in secure laboratory facilities. We would like to store any blood that is left over after we finish your lab tests in a facility which will provide secure storage. We may use the specimens in future studies. We will link the study data with the blood samples using only your ID number, but will not report back these future analyses. Even if you decide not to let us store your blood for future use, you can still be in this current study. **All data will be maintained for approximately 5 years in hard copy with access limited to only authorized individuals.** The electronic data will be securely stored indefinitely. Unauthorized access will be reported to the relevant parties (**participants, stakeholders**). Electronic data will be saved on a device that has the appropriate security safeguards (password protection, etc).

E. DIRECT BENEFITS

You will receive the test results in writing, which you can send to your physician. We will indicate whether any results are of concern. If abnormalities are found, you will be referred to your family physician.

F. COSTS

There is no cost to you for participating in this research, aside from the transportation costs of coming to the appointment. Transportation costs involved in come to the field office will not be reimbursed. Medical care will not be provided by the researchers or research team nor will medical care costs be covered.

G. COMPENSATION

You will be presented with a \$50 Wal-Mart gift card, as a token of appreciation for your participation in the study. **Early withdrawal from the study or incompleting of major parts of the study will not be compensated monetarily.**

H. ALTERNATIVES

The alternative is not to participate in the research.

I. QUESTIONS

You have spoken with Professor Rosemarie Bowler or one of her collaborators about this study and have had your questions answered. If you have any further questions about the study, you may contact the researcher by email at rbowl@sfsu.edu or by phone at 510-236-5599. Questions about your rights as a study participant, or comments or complaints about the study also may be addressed to the Office for the Protection of Human Subjects at San Francisco State University, at 415-338-1093 or protocol@sfsu.edu.

J. CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY. You are free to decline to participate in this research study. You may withdraw from this study at any point without penalty. Even if you sign, you may stop at any time. Your decision to take part in this research will have no influence on your present or future status at San Francisco State University.

Name _____

Signature _____
Participant

Date _____

Signature _____
Researcher

Date _____

I consent to the storage and future use and analyses of my blood. _____

Initial

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Why is this authorization required?

The US Government has issued a new rule, called the Privacy Rule, effective April 14, 2003. This rule requires Rosemarie Bowler Ph.D. and her colleagues to safeguard your Protected Health Information. Protected Health Information also includes information about you that could be used to link your identity to your health information. It also includes the information in your medical record. Your medical and health information will remain private as far as any identification of your name and will be used in the research database using only your ID number. However, to further protect your personal health information and to satisfy governmental rules, you are asked to also sign this **Health Insurance Portability and Accountability Act** (HIPAA) Consent, which will also be stored separate from the research data files.

The purpose of this section is to explain to you how Rosemarie Bowler Ph.D. and her research colleagues propose to use and disclose your health information for the purpose of this study. None of your health information gained in this current research study will be used or disclosed without your written permission.

Must you agree to this authorization to participate in the research?

To participate in this research study, you must agree to authorize the use and disclosure of your health information as described above. If you do not approve this use, you cannot participate in this study.

Why will your health information be used or disclosed for this study?

Rosemarie Bowler Ph.D. and research colleagues who are part of the team, consisting of neurologists, a toxicologist, neuropsychologists and experts on exposure, will use your health information to conduct the study, monitor your health status, and determine research results. Your health information will be used in the research study to identify if certain illnesses occur more often with certain levels of Mn air emissions and levels of Mn in blood. Your health information will not be disclosed outside **Professor** Bowler's research as part of this study, unless required by law. You will receive a letter notifying you of any abnormal results of the study if this will be determined by a qualified doctor who will review your results and will be working with the research team.

Who will use your information, and what is the purpose of this use?

If you sign this authorization, Professor Bowler and her research team may use your health information. They will use your study research record and information from your neuropsychological/medical record which included laboratory tests, and research observations made during your participation in the study.

Professor Bowler and research team may also disclose your health information to research colleagues other than the investigators, who may be asked to rate your results without any identifiers. These persons will be bound under the same confidentiality rules as the investigators of the study.

When will this authorization expire?

This authorization will expire at the end of this research study.

Can you withdraw the authorization?

At any time during this study, you may decide that you no longer want to have your information used or disclosed as part of this study. If so, you must write a letter stating that you withdraw your authorization and send it to: Rosemarie Bowler Ph.D., 8371 Kent Drive, El Cerrito, CA 94530.

If you withdraw your authorization, you may be required to end your participation in the study.

If required by research procedures, Rosemarie Bowler Ph.D. and the other researchers may continue to use health information that was obtained before you withdrew your authorization unless you specifically request to have your data removed.

Even if you withdraw your authorization, Rosemarie Bowler Ph.D. and her colleagues are required by law to record and report anything that relates to the safety of others.

What will happen to my information after it is disclosed?

Professor Bowler's research team will use and disclose your health information only as permitted by you in this authorization. However, collaborating investigators will have signed a confidentiality agreement.

Will you get a copy of authorization?

The researcher who is obtaining this authorization form must give you a copy of this form after you sign it.

Authorization signatures

Your signature indicates that this authorization has been explained to you, all of your questions have been answered, and you agree to allow the use and disclosure of your health information for the research as described below.

Signature of Participant

Date

Name of Participant